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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MICHAEL BEST & FRIEDRICH, LLP
ONE SOUTH PINCKNEY STREET
P O BOX 1806
MADISON, WI 53701

EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/647,711	GOUELI, SAID A.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2 IDSs*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-20 are pending .

Response to restriction requirement filed 09/30/05 is acknowledged. Applicant elected, without traverse, Group II, claims 11-15. Claims 1-10, 16-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 1-10, 16-20 is requested.

Sequence Listing

It is noted that peptide sequences in specification are not followed by corresponding SEQ ID Nos. See p.29.

37 CFR 1.821 requires that:

> Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing " in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

See also MPEP 2422.

Applicant is requested to provide SEQ ID Nos for peptide sequences in specification.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11, step b) requires "inhibitor region" of the alkyl peptide to be substantially homologous to the binding domain of the first protein,. However, as the preceding part of the claims addresses a plurality of binding domains of the first protein ("at least one binding domain"), it is not clear which of the binding domains the inhibitory domain of the peptide is supposed to be homologous to.

Claims 14,15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims refer to claim 10 as the base claim; however, claim 10 is not directed to a method.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of certain alkyl peptides as inhibitors of interaction of anchor protein (AKAP) with cAMP-dependent protein kinase A (PKA), does not reasonably provide enablement for use of any random alkyl peptides as an inhibitor of binding of two intracellular proteins. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The scope of the claims encompasses inhibition of any two intracellular proteins by a peptide having unspecified homology to a binding domain of one of proteins. and an alkyl chain. The specification provides examples of particular peptides (p.19, Table) and some other preferred embodiments (p.17-20). However, there is no guidance on how to select any randomly taken alkyl amide peptide, what is a core structure required for an inhibitory activity, and what two proteins are to be inhibited by such peptide derivative.

In view of the above, it is the Examiners position that with the insufficient guidance and working examples and in view of unpredictability and the state of art one skilled in the art could not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

Claim Rejections - 35 USC § 103.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-15 are rejected under 35 U.S.C. 103(a) as obvious over Carrera (Dev. Biol., 1994, 165, 272-84; reference AT) in view of admitted prior art (specification, p. 19, lines 29-34) and further in view of Lockerbie (US Patent 5,744,354; reference AC).

Carrera teaches that protein tyrosine phosphorylation is a part of a signal transduction cascade regulating mammalian sperm motility and capacitation. In particular, tyrosine phosphorylation phosphorylates A Kinase Anchor Proteins (AKAP), that sequester protein kinase A to subcellular locations.

AKAP fragments are known inhibitors of PKA. See references cited in specification, p. 19, lines 29-34.

It would be *prima facie* obvious to one skilled in the art to be motivated to inhibit cAMP signalling cascade in sperm cells in situations when inhibiting sperm is desirable (i.e., for contraceptive purposes). More specifically, one would be motivated to inhibit PKA anchoring in sperm as it is an initial step in PKA-cAMP signalling cascade. Furthermore, one would be motivated to use any known peptide inhibitor of PKA anchoring, and, specifically, AKAP fragments which are described in the prior art as binding to inhibit anchoring of PKA.

Further, Lockerbie teaches that anchoring of PKA can be inhibited by peptide SEQ ID No.:9 (the referenced peptide comprises SEQ ID 1(underlined) of the instant invention):

DLIEEAASRIVDAVIEQVKAAGA

See col. 5, lines 40-62; claim 4.

As to modifying a peptide with an acyl moiety, because the peptide inhibitors would be intended to target intracellular protein, it would be *prima facie* obvious to one skilled in the art to be motivated to modify the peptide to facilitate its passage into a cell. (Lockerbie (US Patent 5,744,354) teaches that in order to facilitate passage into a cell peptides may be acylated with lipophilic agents, such as myristic acid (col. 5, lines 60-62; col. 6, lines 30-33). Acylation of amino terminus of a peptide, for example with myristic acid, will produce a derivative addressed in the instant claims as an "alkyl peptide" wherein alkyl moiety having a carbonyl terminus is attached to N-terminus of peptide moiety.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim of U.S. Patent No. 6,610,657. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the referenced claim(s) because the examined claim is either anticipated , or would have been obvious over, the reference claim(s). See, e.g., *In re* Berg,140 F.3d 1428,46 USPQ2d 1226 (Fed. Cir.1998); *In re Goodman*,11 F.3d 1046,29 USPQ2d 2010 (Fed. Cir.1993); *In re Longi*, 759 F.2d 887,225 USPQ 645 (Fed. Cir.1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '657 claims teach use of alkyl peptides to inhibit binding of cAMP-dependent protein kinase A by A-kinase anchoring protein.

Conclusion.

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb